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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/689,149

10/20/2003

Miri Seiberg

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EXAMINER

PACKARD, BENJAMIN J

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

06/22/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/689,149	Applicant(s) SEIBERG ET AL.	
	Examiner Benjamin Packard	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) 5-8, 10-12, 14-16, 21-28 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 9, 13, 17-20, 29 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/04/09 has been entered.

Applicants' arguments, filed 03/04/09, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. With regards to Claim 33 being rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and Claim 33 being rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, (where the limitations of claim 33 are now amended into pending claim 1), the rejections are withdrawn as Examiner is persuaded that the term Kunitz-type soybean trypsin inhibitor appears to be an accepted pseudonym of the term soybean trypsin inhibitor and the family of Kunitz-type soybean trypsin inhibitors appears to be limited to those extracted from soybean via the method taught by Kunitz.

The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 102

Claims 1-4, 13, and 17-20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Novogen Res. Pty. Ltd (WO 99/36050 ('050), see Applicants IDS dated 7/12/04 sheet 12).

Applicants assert that the method of extraction from the '050 application requires the process according to WO 93/23069 ('069), which Applicants assert requires heating the soybean plant product, as illustrated in Example 2 of '069. Additionally, applicant's state '069 is concerned with using isoflavon compounds and phyto-oestrogen compounds, not the proteins of the instant claims.

While Applicants appear to focus heavily on the disclosure of '069, Examiner again notes that the cited art, '050, explicitly teaches the extract may be prepared according to WO93/23069. Then '050 goes on to explicitly state, the soy extract is done by a mixture of organic solvents (such as ethanol) and water, without any disclosure of application of heat. As such, the process specifically disclosed by '050 is not limited by the disclosure of '069, but instead the specific teaching of '050 is directed to the use of organic solvents used to extract the product, with no teaching that heat must be applied. Where the same steps made obvious by the prior art are used in the instant application, it is reasonably expected that the resulting process of '050 will have the required non-denatured Kunitz-type soybean trypsin inhibitor.

Even if Examiner does look to the process disclosed in '069, Applicants discussion of Example 2 applies heat to make the hull brittle, not to heat the

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cotylenonds or hypocotyl. No evidence is presented which suggests heating of the hull to ease hull removal will cause denaturing of the product within the hull. Once the hull is removed, Example 2 does not teach how to extract, apparently relying on the process of Example 1, which specifically teaches the use of an organic solvent mix. While the overall process and invention of '069 is directed to other components of the soybean extract, the extract is not limited to the desired compounds, given an extract will reasonably be expected to contain all compounds which are released from soybean upon extraction, whether recognized at the time or not. Nor is '069 limited to removing the hull of the soy bean, which may be done by other obvious means, such as compression.

Claim Rejections - 35 USC § 103

Claims 9 and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Novogen Res. Pty. Ltd as applied above (WO 99/36050, see Applicants IDS dated 7/12/04 sheet 12).

Applicants again assert '050 does not teach the use of non-denatured Kunitz-type soy product.

See discussion above with respect the soy product disclosed in '050.

Claims 1-4, 9, 13, 17-20, and 29 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shapiro et al (WO 99/04752) in view of Kunitz (J. Gen. Physiol. 29 (1946) 149-154).

Applicants assert '752 is directed to changing skin pigmentation and affecting melanogenesis, rather than the instantly claimed method of reducing the risk of cutaneous tumor development. Specially, Applicants assert the application of the composition of '752 is applied after the skin has been exposed to UVB, and also suggest that is teaching away. Applicants also assert the preamble breathes life into the claim.

First, '752 is not limited as Applicants assert, but instead, looking to claim 1 of '752, the method is simply directed to effecting changes in skin pigmentation by administering a compound, which may include fractions of undenatured soybean extract (claim 16). The affected PAR-2 pathway is a limitation of the compound, not the method; therefore the application of the composition is not limited to only patients with already damaged skin. As such, the patient population is not limited to patients who have skin damage due to ultraviolet radiation, but simply patients who desire a change in skin pigmentation generally.

Second, even if '752 is limited to patients with some sun damage, it is reasonably expected that application of the composition will also be applied to skin which surrounds the damaged skin, i.e. undamaged skin. As such, the method of reducing the risk of cutaneous tumor development would be obvious, given the same agents are administered to the same patient population.

Finally, where the instant preamble defines the method as reducing the risk of cutaneous tumor development, the simple act of administering the agent to the proper patient population appears to meet the limitation. Here, the same agent is made obvious to administer to patients, which would reasonably be expected to reduce the risk of cutaneous tumor development, given everyone is at risk of cutaneous tumors (even those with some tumors are at risk of additional tumors at undamaged skin sites).

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Packard whose telephone number is 571-270-3440. The examiner can normally be reached on M-F 8-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Benjamin Packard/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612